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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,887	11/06/2002	Chaim M. Roifman	280502000200	2918

25225 7590 01/02/2004

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EXAMINER	
SAEED, KAMAL A	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,887	ROIFMAN ET AL.	
	Examiner	Art Unit	
	Kamal A Saeed	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-22* is/are allowed.

6)☒ Claim(s) *23-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-37, are currently pending in this application.

Information Disclosure Statement

Applicant's Information Disclosure Statements, filed on June 23, 2003 and June 04, 2002 has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Priority

This application is a national-phase application of PCT Patent Application No. PCT/CA00/00266 filed on March 13, 2000, which claims the benefit of foreign priority to Canadian Application No. 2,265,396, filed March 12, 1999.

Response to Restriction

Applicants' election with traverse of Group I, claims 1-22, drawn to products formula I, wherein $\mathbf{R_1}$-$\mathbf{R_3}$ are as defined and $\mathbf{R_4}$ is substituted or unsubstituted phenyl in response filed October 22, 2003 is acknowledged. The traversal is on the ground(s) that the examiner has not provided adequate reasons and or examples to support a conclusion of patentable distinctness between the identified groups. Applicants' argument is persuasive and the restriction requirement mailed August 31, 2003 is hereby withdrawn.

Since the product is found allowable, in accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), the withdrawn claims 23-36, directed to method of use have been rejoined with the product commensurate in scope therewith..

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-36, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for treating specific neoplastic disorders or cell proliferative disorder does not reasonably provide enablement for all neoplastic disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The Nature of the Invention

The nature of the invention in claims 23 and 36 is to a method of treatment of neoplastic disorders or cell proliferative disorder.

The State of the Prior Art

"Neoplastic disorder" is a general term that embraces many different diseases, for example, leukemia, lymphoma, sarcomas and so forth. As defined, the compounds read on treating all types of "neoplastic disorder" which is broader than the enabling disclosure. Chemotherapeutic agents are frequently useful against a specific type of cancer or neoplasm and especially with the unpredictability in the state of the art there are no drugs broadly effective

against all forms of cancer, (Carter, S.K. et al., Chemotherapy of Cancer; Second Edition; John Wiely & Sons: New York, 1981; Appendix C).

The level of skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

The predictability or lack thereof in the art

Because of high level of unpredictability associated with treatment of neoplastic disorders or cell proliferative disorders, a greater amount of evidentiary support is needed to fully satisfy the requirement of 35 U.S.C 112, first paragraph. It is noted that pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present

The specification discloses methods of treating diseases such as leukemia

and lymphoma using the compounds described in the specification. The compounds which are disclosed in the specification, which have data regarding treatment of diseases such as leukemia and lymphoma (pages 12-15), have no pharmacological data regarding the treatment of ovarian cancer or prostate cancer. Merely stating that the instant compounds are useful for treating all neoplastic disorders does not establish usefulness of the invention absent art-recognized correlation between such tests and the ultimate use.

The presence or absence of working examples

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that compounds fall within the scope of a claim will posses the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724. The instant specification at most only provide one example for treating diseases such as leukemia.

The breadth of the claims

As defined the claims read on treating and preventing diseases such as Alzheimer's disease, learning deficit, memory loss, attention deficit, memory loss, Parkinson's disease and Huntington's disease which is broader than the enabling disclosure.

The quantity of experimentation needed

Based on the unpredictable nature of the invention and the state of the prior art and the breadth of the claims, one of ordinary skill in the art would be burdened with undue "experimentation study" to determine whether the claimed compounds would treat diseases such as colon cancer. Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but

compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which compounds would treat for example colon cancer by the method encompassed in the instant claims, with no assurance of success.

It is suggested that the claims either be limited to the diseases actually contemplated in the specification or enable the full range of this term.

Allowable Subject Matter

Claims 1-23 are allowable over the prior art.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal Saeed whose telephone number is (703) 308-4592. The examiner can normally be reached on Monday-Friday from 8:00 AM – 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308 4537. The unofficial fax phone for this group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signiture, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-2286.

Kamal Saeed

Kamal Saeed, Ph.D.
Patent Examiner, AU 1626